

Claims Amendment and Claims Listing:

1. (Original) An applicator device for facilitating radiation treatment of a cavity within human tissue, comprising:  
an inflatable balloon configured to be inserted into the cavity,

a lumen connected to the balloon for inflating the balloon when positioned within the cavity, and

the balloon being formed of a flexible, expandable material which includes a sufficient quantity of an x-ray-absorbing material that when inflated and inside the cavity, the balloon's peripheral edges, essentially tangential to a line of sight in an x-ray image, can be seen in such an x-ray image taken from outside the cavity.

2. (Original) The applicator device of claim 1, wherein the x-ray absorption density of the balloon wall is such as to absorb about 5% of radiation during treatment, at a selected energy level of the radiation.

3. (Original) The applicator device of claim 1, wherein the x-ray absorbing material is integrated into the flexible, expandable material of the balloon and comprises about 3% to 5% by weight barium sulfate.

4. (Original) The applicator device of claim 1, wherein the x-ray absorbent material of the balloon is sufficiently low in concentration as to absorb no more than about 5% of x-ray radiation having an energy of about 15-40 kV at the balloon surface, when the x-ray penetrate the balloon approximately normal to the balloon surface.

5. (Original) The applicator device of claim 1, wherein the x-ray absorbing material in the balloon is of such concentration that, in an x-ray view of the balloon, the portion of the x-ray view at essentially a tangent of the balloon is a factor of about 15 to 25 times more absorbent, due to an effective path length about 15 to 25 times greater, than a portion normal to the balloon wall.

6. (Original) The applicator device of claim 1, wherein the balloon has a wall thickness which varies at different portions of the balloon, causing higher x-ray absorption in some areas than others, to control dose distribution to different areas of the tissue to be treated when x-ray radiation is delivered from within the balloon.

7. (Currently Amended) A method for determining the position of a balloon applicator placed in a cavity within human

tissue, comprising:

providing an applicator device including an inflatable balloon configured to be inserted into the cavity, a lumen connected to the balloon for inflating the balloon when positioned within the cavity, and the balloon being formed of a flexible, expandable material which includes a sufficient quantity of an x-ray absorbing material that when inflated and inside the cavity, the balloon's peripheral edges, essentially tangential to a line of ~~site~~ sight in an x-ray image, can be seen in such an x-ray image taken from outside the cavity,

inserting the applicator with the balloon into the cavity, and inflating the balloon using the lumen, and

forming an x-ray image of the inflated balloon in the cavity and detecting the position of the balloon relative to the surrounding tissues by observation of the walls of the balloon which appear in the x-ray image essentially along the tangent to the balloon wall, where x-ray absorption is maximum.

8. (Original) The method of claim 7, wherein the x-ray absorbing material in the balloon is of such concentration that, in an x-ray view of the balloon, the portion of the x-ray view at essentially a tangent of the balloon is a factor of about 15 to 25 times more absorbent than a portion normal to the balloon wall.

9. (Original) The method of claim 7, wherein the x-ray absorbing material comprises about 3% to 5% by weight barium sulfate in the balloon wall material.

10. (Original) The method of claim 7, wherein the balloon has a wall thickness which varies at different portions of the balloon, causing higher x-ray absorption in some areas than others, to control dose distribution to different areas of the tissue to be treated when x-ray radiation is delivered from within the balloon.

11. (Original) An applicator for radiation treatment of a cavity within human tissue, comprising:

an inflatable balloon insertable into the cavity in a deflated state,

a lumen connected to the balloon for inflation of the balloon following insertion into the cavity and for receiving a source of radiation inserted into the lumen,

the balloon being configured to reach a desired general shape when inflated, and

the balloon having a wall thickness which varies in different parts of the balloon so as to control the inflated shape of the balloon, thicker areas tending not to expand as extensively as thinner areas of the balloon wall.

12. (Original) The applicator of claim 11, wherein some portions of the balloon wall have a thickness which is a factor of about two times thicker than other areas of the balloon wall.

13. (Original) The applicator of claim 11, wherein the variation in balloon wall thickness is such as to restrict the expansion of thicker regions of the balloon, when the balloon is inflated, to about 70% compared to the same balloon geometry without the wall thickness variations.

14. (Original) The applicator of claim 11, wherein the balloon wall thickness variation is configured so as to produce the general shape of a football, a hotdog, a pear or a truncated cone.

15. (Original) An applicator for radiation treatment of a cavity within human tissue, comprising;

an inflatable balloon insertable into the cavity in a deflated state,

a flexible shaft connected to the balloon for inflation of the balloon following insertion into the cavity and for receiving a source of radiation,

the balloon being configured to reach a desired general shape when inflated, so as to engage a wall of the balloon

against tissue surrounding the cavity, and

wherein the balloon wall has one or more ribs configured to restrict expansion along the lines of the ribs and thus to control the shape of the balloon upon inflation, to the desired general shape.

16. (Original) The applicator of claim 15, wherein the flexible shaft is arranged longitudinally relative to the balloon, and wherein at least one said rib extends circumferentially on the balloon, generally in a plane transverse to the flexible shaft.

17. (Original) The applicator of claim 15, wherein the rib or ribs are formed on the inside of the balloon wall.

18. (Original) The applicator of claim 15, wherein the rib or ribs are formed on the outside of the balloon wall.

19. (Original) The applicator of claim 15, further including a surgical drain comprising a plurality of said ribs arranged on the outside surface of the balloon so as to form channels along which seroma and other fluids from the cavity can flow in a direction toward an opening of the cavity into which the applicator has been inserted.

20. (Original) The applicator of claim 19, wherein the flexible shaft includes drain holes for withdrawing liquids from the cavity via at least one duct in the shaft and wherein the ribs are arranged to form said channels in a way to conduct liquids toward the drain holes.

21. (Original) The applicator of claim 20, wherein the flexible shaft includes at least one additional drain opening at a distal end of the flexible shaft for collecting fluids from the cavity.

22. (Original) An applicator for use in administering radiation to a cavity in living tissue, comprising:

at least two inflatable balloons positioned side by side and connected so as to be insertable into the tissue cavity together when collapsed, and a flexible shaft connected to the balloons with an inflation lumen for the balloons, at least one of the balloons having a guide within the balloon connected to a channel in the shaft for receiving a radiation source at a peripheral position in the balloon to deliver radiation to walls of the cavity.

23. (Original) The applicator of claim 22, wherein each balloon has a guide within the balloon for receiving a radiation

source.

24. (Original) The applicator of claim 22, wherein the balloons are bonded together.

25. (Original) The applicator of claim 22, wherein at least three balloons are included in the applicator, secured to the flexible shaft which is located generally centrally in the applicator, and each balloon carrying a guide for receiving a source of radiation.

26. (Original) The applicator of claim 25, wherein the plurality of balloons are radially disposed around the flexible shaft and are of different sizes when inflated, whereby radiation sources can be located along the walls of an irregularly shaped cavity.

27. (Original) The applicator of claim 26, with the balloons in the cavity and inflated and with an isotope radiation source in the guide, irradiating the cavity.

28. (Original) The applicator of claim 26, the applicator including at least four balloons radially disposed around the flexible shaft, and the applicator inserted into a tissue cavity



and the balloons inflated, the cavity being irregular in shape and the balloons together assuming generally the shape of the cavity and extending into irregularities.

29 . (Original) The applicator of claim 22, inserted into the tissue cavity and the balloons inflated, in combination with an isotope radiation source in the guide.

30. (Original) The applicator of claim 22, inserted into the tissue cavity and the balloons inflated, in combination with a miniature switchable x-ray tube radiation source in the guide.

31. (Original) An applicator for use in administering radiation to a cavity in living tissue, comprising;

outer and inner inflatable balloons, the inner balloon being positioned within the outer balloon and the balloons being connected and insertable into the tissue cavity when collapsed,

a shaft connected to the balloons with an inflation lumen for the balloons, and the shaft extending into the inner balloon and including a channel for receiving a radiation source to deliver radiation to walls of the cavity,

the outer wall of the inner balloon being substantially in contact with the inner wall of the outer balloon and bonded there to except at a particular desired area of the balloon where the

two balloons are unbonded, and

the unbonded area between the two balloons being filled with a contrast medium to limit radiation passing through said area so as to shield cavity tissue immediately adjacent to said area.

32. (Original) An applicator for use in administering radiation to a cavity in living tissue, comprising:

an inner balloon and an outer balloon, and a flexible shaft with inflation lumens connected to the inner and outer balloons for inflation of each balloon, and

the inner balloon having a plurality of guides secured to the balloon, each guide for receiving a radiation source at a peripheral position relative to the inner balloon, to deliver radiation to walls of the cavity,

whereby expansion of both the outer balloon and the inner balloon is controllable, and whereby the positions of the guides and thus of radiation sources inserted into the guides is controllable so that radiation dose profile to the cavity can be manipulated as needed.

33. (Original) The applicator of claim 32, inserted into the tissue cavity and the balloons inflated, and further including an isotope radiation source in at least one of the guides.

34. (Original) The applicator of claim 32, inserted into the tissue cavity and the balloons inflated, and further including miniature switchable x-ray tube sources in at least some of the guides.

35. (Original) An applicator for administering radiation therapy to a surgical cavity in living tissue, comprising:  
an expandable balloon for positioning within the cavity,  
a flexible shaft including a lumen connected to the balloon for delivering a fluid to inflate the balloon,  
the shaft being highly flexible and pliable at least in an outer or proximal portion of the shaft, positioned to be at the exterior of the cavity, so as to be foldable down adjacent to the skin of a patient during periods when radiation therapy is not being administered, and  
a radially extending seal secured to the exterior of the flexible shaft, the seal being soft and pliable and being generally thin and flat and having a size and area much larger than the diameter of the flexible shaft to permit adhering of the seal to the patient's skin surrounding a surgical opening leading to said cavity against leakage of seroma and other liquids from the wound.

36. (Original) The applicator of claim 35, wherein the seal comprises a circular disc of silicone.

37. (Original) The applicator of claim 35, wherein the seal has a central hole that fits closely over the flexible shaft, essentially sealing against the exterior of the flexible shaft but being slidable along the flexible shaft such that the seal can be moved longitudinally on the lumen for adjustment while still maintaining an essentially sealed relationship with the flexible shaft.

38. (Original) The applicator of claim 35, wherein the seal comprises a round disc having a generally radial slit extending to a central hole through which the flexible shaft passes, such that the seal can be installed onto the flexible shaft and can be interchanged.

39. (Original) The applicator of claim 35, wherein the flexible shaft includes a drain channel and at least one hole from the drain channel to the exterior of the flexible shaft, the holes being positioned to be inside the patient's tissue for withdrawal of liquids from the cavity as retained therein by the seal.

40. (Original) The applicator of claim 39, with the flexible shaft folded down at the exterior of the cavity, adjacent to the skin of the patient, the drain channel being effective to drain liquids from the cavity while the tube device is folded down.

41. (Original) An applicator for facilitating radiation treatment of a cavity inside living tissue, comprising:

an inflatable balloon having a collapsed state and an inflated state,

a flexible shaft secured to the balloon and being elongated so as to extend from inside the surgical cavity to outside the surgical cavity when installed, said flexible shaft having a lumen for introducing a fluid to the balloon to inflate the balloon,

surface relief means on the exterior of the balloon for providing channels when the balloon is inflated, to allow the flow of liquids from the surgical cavity toward the exit of the surgical cavity, and

at least one drain channel provided in the flexible shaft, positioned to receive draining liquids from the surgical cavity, and means in the flexible shaft for conducting said liquids out of the surgical cavity through the drain channel.

42. (Original) The applicator of claim 41, wherein the flexible shaft has a central longitudinal channel and a series of outer longitudinal channels arranged generally in an annular array around the central longitudinal channel, at least one of the outer channels comprising said drain channel and being open at a distal end of the flexible shaft to collect liquid.

43. (Original) The applicator of claim 42, wherein the flexible shaft has entry holes proximal of the balloon, communicating with at least one drain channel, providing another location to collect drain liquids.

44. (Original) The applicator of claim 41, wherein a proximal end of the flexible shaft is branched, one branch having said drain channel and adapted to an aspirator to draw off liquids, another branch having said lumen for inflation of the balloon, and a further branch having a channel for insertion of a radiation delivering source, through said central longitudinal channel.

45. (Original) The applicator of claim 44, wherein said lumen comprises one of the outer channels.

46. (Original) The applicator of claim 44, wherein the balloon includes guides to receive the radiation delivery source, said guides connected to said central longitudinal channel and said further branch.

47. (Original) The applicator of claim 41, wherein the surface relief means comprises longitudinally extending ridges on the exterior of the balloon, providing channels between adjacent ridges.

48. (Original) The applicator of claim 47, wherein the ridges are interrupted in their length, providing for cross flow of liquids between channels.

49. (Original) The applicator of claim 41, wherein the surface relief means comprises bumps extending outwardly on the exterior of the balloon.

50. (Original) The applicator of claim 41, wherein the surface relief means comprises grooves extending inwardly on the exterior surface of the balloon.

51. (Original) An applicator device for facilitating radiation treatment of a cavity within human tissue, comprising:

an inflatable balloon configured to be inserted into the cavity when uninflated,

a flexible shaft connected to the balloon for inflating the balloon when positioned within the cavity, and

the flexible shaft having a stiffener on a portion of the shaft within the balloon, the stiffener comprising a sleeve tightly engaging over the other surface of the flexible shaft.

52. (Original) The applicator of claim 51, wherein the stiffener comprises a heat shrink material over the shaft within the balloon.

53. (New, corresp. to '410 claim 39) A device for irradiating tissue adjacent a body cavity, comprising:

a. an elongated shaft having a proximal shaft section, a distal shaft section, a first lumen extending through the proximal shaft section and into the distal shaft section for receiving and advancing an irradiation source to an irradiation location in the distal shaft section;

b. at least one vacuum port in the distal shaft section which is configured to directly open to and be in fluid communication with the body cavity and at least one vacuum lumen extending to and in fluid communication with the at least one vacuum port; and



c. a single expandable member which surrounds the irradiation location on the distal shaft section, which has a first configuration for passage to the body cavity and which has a second expanded configuration with larger transverse dimensions than the first configuration to receive the tissue lining of the body cavity upon the application of a vacuum to the body cavity through the vacuum port and to shape the body cavity to the expanded expandable member in order to effectively receive therapeutic irradiation.

54. (New, corresp. to '410 claim 40) The device of claim 53, wherein at least one vacuum port is proximal to the expandable member.

55. (New, corresp. to '410 claim 41) The device of claim 53, wherein at least one vacuum port is distal to the expandable member.

56. (New, corresp. to '410 claim 42) The device of claim 53, wherein at least one vacuum port is proximal to the expandable member and at least one vacuum port is distal to the expandable member.

57. (New, corresp. to '410 claim 43) The device of claim 53, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port proximal to the expandable member.

58. (New, corresp. to '410 claim 44) The device of claim 53, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port distal to the expandable member.

59. (New, corresp. to '410 claim 45) The device of claim 53, wherein the expandable member is an inflatable balloon with an interior configured to receive inflation fluid.

60. (New, corresp. to '410 claim 46) The device of claim 59, wherein the shaft has an inflation lumen which extends through the proximal shaft section to the distal shaft section and which is in fluid communication with the interior of the balloon.

61. (New, corresp. to '410 claim 47) The device of claim 59, wherein the inflatable balloon has at least one rib on the exterior thereof.

62. (New, corresp. to '410 claim 48) The device of claim 61, wherein the rib is configured to space at least part of the tissue adjacent the cavity away from an exterior surface of the balloon.

63. (New, corresp. to '410 claim 49) The device of claim 59, wherein the balloon is formed at least in part of a flexible material.

64. (New, corresp. to '410 claim 50) The device of claim 63, wherein the flexible material is formed at least in part of a polymeric material.

65. (New, corresp. to '410 claim 51) The device of claim 64, wherein the polymeric material is a biocompatible polymer.

66. (New, corresp. to '410 claim 52) The device of claim 64, wherein the polymeric material is at least in part radiation-resistant.

67. (New, corresp. to '410 claim 53) The device of claim 64, wherein the polymeric material is selected from the group consisting of a polyolefin, polyethylene, polypropylene, polyurethane, polyester, polyvinylchloride, polystyrene, nylon,

latex rubber, silicon rubber and a thermoplastic polymer.

68. (New, corresp. to '410 claim 54) The device of claim 59, wherein the balloon is formed at least in part of an elastic material.

69. (New, corresp. to '410 claim 55) The device of claim 59, wherein the balloon is formed at least in part of an inelastic material.

70. (New, corresp. to '410 claim 56) A method for irradiating tissue lining of a patient's body cavity, comprising:

a. providing an irradiation device which has an elongated shaft, an expandable member on a distal portion of the shaft and an interior within the expandable member configured to receive an irradiation source;

b. advancing the irradiation device within the patient until the expandable member thereof is disposed within the body cavity;

c. expanding the expandable member within the body cavity to a desired expanded configuration;

d. conforming the tissue lining of the body cavity about the expanded configuration of the expandable member by applying a vacuum to an exterior region about the expandable member through

the vacuum port and;

e. introducing an irradiating source into the interior of the expandable member at an irradiation site; and

f. irradiating the conforming tissue lining of the body cavity about the expanded shape of the expandable member by the irradiating source within the interior of the expandable member.

71. (New, corresp. to '410 claim 57) The method of claim 70, wherein irradiating source is a radioactive material.

72. (New, corresp. to '410 claim 58) A device for irradiating a tissue lining defining at least in part a body cavity, comprising:

a. an elongated shaft having a proximal shaft section, a distal shaft section and an irradiation location in the distal shaft section;

b. at least one vacuum port in the distal shaft section configured to directly open to and be in fluid communication with the body cavity and at least one vacuum lumen extending to and in fluid communication with the at least one vacuum port in the distal shaft section; and

c. A single expandable member which surrounds the irradiation location on the distal shaft section, which has a first configuration for passage to the body cavity and which has

a second expanded configuration of predetermined shape with larger transverse dimensions than the first configuration to receive the tissue lining of the body cavity upon the application of a vacuum to the body cavity through the vacuum port and to thereby shape the body cavity to receive therapeutic irradiation.

73. (New, corresp. to '410 claim 59) The device of claim 72, wherein at least one vacuum port is proximal to the expandable member.

74. (New, corresp. to '410 claim 60) The device of claim 72, wherein at least one vacuum port is distal to the expandable member.

75. (New, corresp. to '410 claim 61) The device of claim 72, wherein at least one vacuum port is proximal to the expandable member and at least one vacuum port is distal to the expandable member.

76. (New, corresp. to '410 claim 62) The device of claim 72, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port proximal to the expandable member.

77. (New, corresp. to '410 claim 63) The device of claim 72, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port distal to the expandable member.

78. (New, corresp. to '410 claim 64) The device of claim 72, wherein the expandable member is an inflatable balloon with an interior configured to receive inflation fluid.

79. (New, corresp. To '410 claim 65) The device of claim 72, wherein the shaft has an inflation lumen which extends through the proximal shaft section to the distal shaft section and which is in fluid communication with the interior of the balloon.

80. (New, corresp. to '410 claim 66) The device of claim 72, wherein the inflatable balloon has at least one rib on the exterior thereof.

81. (New, corresp. to '410 claim 67) The device of claim 80, wherein the rib is configured to space at least part of the tissue adjacent the cavity away from an exterior surface of the balloon.

82. (New, corresp. to '410 claim 68) The device of claim 78, wherein the balloon is formed at least in part of a flexible material.

83. (New, corresp. to '410 claim 69) The device of claim 78, wherein the balloon is formed at least in part of an elastic material.

84. (New, corresp. to '410 claim 70) The device of claim 79, wherein the balloon is formed at least in part of an inelastic material.

85. (New, corresp. to '410 claim 71) The device of claim 72, wherein the flexible material is formed at least in part of a polymeric material.

86. (New, corresp. to '410 claim 72) The device of claim 85, wherein the polymeric material is a biocompatible polymer.

87. (New, corresp. to '410 claim 73) The device of claim 85, wherein the polymeric material is at least in part radiation-resistant.



88. (New, corresp. to '410 claim 74) The device of claim 85, wherein the polymeric material is selected from the group consisting of a polyolefin, polyethylene, polypropylene, polyurethane, polyester, polyvinylchloride, polystyrene, nylon, latex rubber, silicon rubber and a thermoplastic polymer.

89. (New, corresp. to '410, claim 75) A method for therapeutically irradiating tissue lining a patient's body cavity, comprising:

a. providing an irradiation device which has an elongated shaft, an expandable member on a distal portion of the shaft with a first configuration for delivery and a second configuration with an exterior of desired shape having larger transverse dimensions than the first configuration and an inner lumen extending through the elongated shaft leading to an irradiation location within the expandable member;

b. advancing the irradiation device within the patient with the expandable member in the first configuration until the expandable member thereof is disposed within the body cavity;

c. expanding the expandable member within the body cavity to a second configuration;

d. conforming the tissue lining the body cavity to the exterior of the expandable member in the second configuration within the body cavity; and

e. irradiating tissue conforming to the exterior of the expandable member by an irradiating source disposed in the irradiation location within the interior of the expandable member in the second configuration.

90. (New, corresp. to '410 claim 76) A method for therapeutically irradiating tissue a patient's body cavity, comprising:

a. the step for providing an irradiation device which has an elongated shaft, an expandable member on a distal portion of the shaft with a first configuration for delivery and a second configuration with an exterior of desired shape having larger transverse dimensions than the first configuration and an inner lumen extending through the elongated shaft leading to an irradiation location within the expandable member;

b. the step for advancing the irradiation device within the patient with the expandable member in the first configuration until the expandable member thereof is disposed within the body cavity;

c. the step for expanding the expandable member within the body cavity to a second configuration;

d. the step for conforming the tissue lining the body cavity to the exterior of the expandable member in the second configuration within the body cavity; and

e. the step for irradiating tissue conforming to the exterior of the expandable member by an irradiating source disposed at the irradiation location within the interior of the expandable member in the second configuration.

91. (New, corresp. to '410 claim 77) A method for therapeutically irradiating tissue lining a patient's body cavity, comprising:

a. providing an irradiation device which has an expandable member with a first configuration for delivery, a second expanded configuration with an exterior of desired shape having larger transverse dimensions than the first configuration and an interior;

b. disposing the irradiation device within the patient's body cavity with the expandable member in the first configuration;

c. expanding the expandable member within the patient's body cavity to the second configuration;

d. applying a vacuum to the patient's body cavity to conform tissue lining the body cavity to the exterior of the expanded expandable member in the second configuration; and

e. irradiating tissue conforming to the exterior of the expandable member by an irradiating source disposed within the interior of the expandable member in the second configuration.

92. (New, corresp. to '410 claim 78) The method of claim 91, wherein the expandable member is contracted within the body cavity and removed from the cavity.

93. (New, corresp. to '410 claim 79) The method of claim 91, wherein the irradiating source is radioactive.

94. (New, corresp. to '410 claim 80) The method of claim 91, wherein the irradiation device has an elongated shaft which extends out of the patient's body cavity when the expandable member is deployed within the patient's body cavity.

95. (New, corresp. to '410 claim 81) The method of claim 94, wherein the elongated shaft has an inner lumen extending therein which is in fluid communication with a port in a distal portion of the irradiation device.

96. (New, corresp. to '410 claim 82) The method of claim 95, wherein the port is distal to the expandable member.

97. (New, corresp. to '410 claim 83) The method of claim 95, wherein the port is proximal to the expandable member.

98. (New, corresp. to '410 claim 84) The method of claim 95, wherein vacuum is applied to the body cavity through the inner lumen of the shaft.

99. (New, corresp. to '410 claim 85) A method for therapeutically irradiating tissue a patient's body cavity, comprising:

a. the step for providing an irradiation device which has an expandable member with a first configuration for delivery, a second expanded configuration with an exterior of desired shape having larger transverse dimensions than the first configuration and an interior;

b. the step for disposing the irradiation device within the patient's body cavity with the expandable member in the first configuration.

c. the step for expanding the expandable member within the patient's body cavity to the second configuration.

d. the step for applying a vacuum to the patient's body cavity to conform tissue lining the body cavity to the exterior of the expanded expandable member in the second configuration; and

e. the step for irradiating tissue conforming to the exterior of the expandable member by an irradiating source disposed within the interior of the expandable member in the

second configuration.

100. (New, corresp. to '410 claim 86) A method for therapeutically irradiating tissue lining a cavity within a patient's body from which tissue has been removed to necrotize residual neoplastic tissue surrounding the cavity, comprising:

a. expanding an expandable member with an exterior surface within the cavity to a configuration having transverse dimensions less than maximum transverse dimensions of the body cavity,

b. applying a vacuum to the patient's body cavity to conform tissue lining the body cavity to the exterior surface of the expanded expandable member, and

c. irradiating tissue conforming to the exterior of the expandable member by an irradiating source within the interior of the expandable member in the expanded configuration.

101. (New, corresp. to '410 claim 87) The method of claim 100, wherein the irradiating source is a radioactive material.

102. (New, corresp. to '410 claim 88) The method of claim 101, wherein the radioactive source has a shape that is different than the shape of the expanded expandable member.

103. (New, corresp. to '410 claim 89) The method of claim 102, wherein the expanded expandable member has a spherical shape.

104. (New, corresp. to '410 claim 90) The method of claim 103, wherein the radioactive source has a cylindrical shape.

105. (New, corresp. to '410 claim 91) The method of claim 100, wherein the tissue conforming to the exterior surface of the expanded expandable member is irradiated by a radioactive source for a preselected time period.

106. (New, corresp. to '410 claim 92) The method of claim 100, wherein the expanded expandable member is contracted within the body cavity and removed from the cavity after tissue lining the body cavity has been irradiated by the radioactive source for a preselected time period.

107. (New, corresp. to '410 claim 93) The method of claim 100, wherein the irradiating source is radioactive.

108. (New, corresp. to '410 claim 94) The method of claim 100, wherein the expandable member has a delivery configuration that has smaller transverse dimensions than the expanded

configuration.

109. (New, corresp. to '410 claim 95) The method fo claim 108, wherein the expandable member is advanced into the body cavity in the delivery configuration.

110. (New, corresp. to '410 claim 96) The method of claim 100, wherein the expandable member is an inflatable balloon.

111. (New, corresp. to '410 claim 97) A method for therapeutically irradiating tissue lining a cavity within a patient's body from which tissue has been removed to necrotize residual neoplastic tissue surrounding the cavity, comprising:

a. the step for expanding an expandable member with an exterior surface within the cavity to a configuration having transverse dimensions less than maximum transverse dimensions of the body cavity,

b. the step for applying a vacuum to the patient's body cavity to conform tissue lining the body cavity to the exterior surface of the expanded expandable member, and

c. the step for irradiating tissue conforming to the exterior of the expandable member by an irradiating source within the interior of the expandable member in the expanded configuration.



112. (New, corresp. to '410 claim 98) An elongated device for irradiating tissue forming at least in part a body cavity, comprising:

a. an elongated shaft having a proximal shaft section, a distal shaft section and an irradiation location in the distal shaft section;

b. a treatment member which surrounds the irradiation location on the distal shaft section and which is configured for deployment within the body cavity; and

c. at least one vacuum port in a distal portion of the device proximal or distal to the treatment member which is configured to directly open to and be in fluid communication with the body cavity and a vacuum lumen leading to the vacuum port to develop a vacuum within the body cavity to conform the body cavity to the treatment member in order to deliver an effective dose of therapeutic irradiation from a radiation source at the irradiation location to tissue forming the body cavity.

113. (New, corresp. to '410 claim 99) The device of claim 112, wherein at least one vacuum port is proximal to the treatment member.

114. (New, corresp. to '410 claim 100) The device of claim 112 wherein at least one vacuum port is distal to the treatment member.

115. (New, corresp. to '410 claim 101) The device of claim 112 wherein at least one vacuum port is proximal to the treatment member and at least one vacuum port is distal to the treatment member.

116. (New, corresp. to '410 claim 103) The device of claim 113 wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port proximal to the treatment member.

117. (New, corresp. to '410 claim 104) The device of claim 114, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port distal to the treatment member.

118. (New, corresp. to '410 claim 106) The device of claim 112, wherein the treatment member is expandable.

119. (New, corresp. to '410 claim 107) The device of claim 118, wherein the expandable treatment member is an inflatable balloon with an interior configured to receive inflation fluid.

120. (New, corresp. to '410 claim 108) The device of claim 119, wherein the shaft has an inflation lumen which extends through the proximal shaft section to the distal shaft section and which is in fluid communication with the interior of the balloon.

121. (New, corresp. to '410 claim 109) The device of claim 119, wherein the inflatable balloon has at least one rib on the exterior thereof.

122. (New, corresp. to '410 claim 110) The device of claim 121, wherein the at least one rib is configured to space at least part of the tissue adjacent the cavity away from an exterior surface of the balloon.

123. (New, corresp. to '410 claim 111) The device of claim 119, wherein the balloon is formed at least in part of a polymeric material.

124. (New, corresp. to '410 claim 112) The device of claim 123, wherein the polymeric material is flexible material.

125. (New, corresp. to '410 claim 113) The device of claim 123, wherein the polymeric material is elastic material.

126. (New, corresp. To '410 claim 114) The device of claim 123, wherein the polymeric material is inelastic material.

127. (New, corresp. to '410 claim 115) The device of claim 123, wherein the polymeric material is a biocompatible polymer.

128. (New, corresp. to '410 claim 116) The device of claim 123, wherein the polymeric material is at least part radiation-resistant.

129. (New, corresp. to '410 claim 117) The device of claim 123, wherein the polymeric material is selected from the group consisting of a polyolefin, polyethylene, polypropylene, polyurethane, polyester, polyvinylchloride, polystyrene, nylon, latex rubber, silicon rubber and a thermoplastic polymer.

130. (New, corresp. to '410 claim 118) The device of claim 123, wherein the polymeric material is polyester.

131. (New, corresp. to '410 claim 119) The device of claim 123, wherein the polymeric material is nylon.

132. (New, corresp. to '410 claim 120) The device of claim 123, wherein the polymeric material is a thermoplastic polymer.

133. (New, corresp. to '410 claim 121) The device of claim 112, wherein the treatment member has a spherical shape.

134. (New, corresp. to '410 claim 122) The device of claim 119, wherein the balloon has a spherical shape in an inflated balloon.

135. (New, corresp. to '002 claim 29) A method for treating tissue adjacent a body cavity containing a treatment assembly, comprising:

applying a vacuum to said body cavity effective to draw said tissue adjacent the body cavity towards said treatment assembly.

136. (New, corresp. to '002 claim 31) A device for enhancing treatment of tissue adjacent a body cavity delivered by a treatment assembly configured for delivering a treatment to tissue adjacent a body cavity, comprising:

enclosure device configured to at least partly enclose a treatment assembly for delivering a treatment to body tissue adjacent a body cavity;

a vacuum conduit; and

a vacuum port operatively connected to said vacuum conduit

configured to provide suction adjacent said treatment assembly when said enclosure device is disposed to at least partly enclose said treatment assembly.

137. (New, corresp. to '002 claim 32) The device for enhancing treatment of tissue adjacent a body cavity delivered by a treatment assembly configured for delivering a treatment to tissue adjacent a body cavity of claim 136, wherein said treatment assembly comprises an inflatable treatment delivery device.